REMARKS

Claims 28-36 were rejected under 35 U.S.C.§112, first paragraph because the specification , while being enabling for a dietary product, said product comprising at least one modified bovine beta-casein selected from the group consisting of recombinant or synthetic caseins which lack SEQ ID NO: 1 and SEQ ID NO: 2 and further lack SEQ ID NO: 3 and 4, methods for the inhibition of molecular mimicry of protein GLUT2 comprising the step of administering to newborns and infants does not reasonably provide enablement for pharmaceutical products.

Reconsideration is requested.

The Examiner has referred to page 5 and 6 of the prior Office Action as containing the reasons for the present rejection and has urged that the "specification fails to provide teachings, evidence or guidance with regard to a correlation between the feeding of newborns and infants the product as claimed" and "no teachings are provided with regard to the target population, for examples, which newborns or individuals would be at risk, or would the product be administered to all individuals".

The Examiner's comments regarding the administering of the claimed product to all individuals ignores the public health benefits of a product, which may not be of benefit to a particular individual, because the individual may never be exposed to the condition for which the product is administered. Materials of this type include vaccines and prophylactic doses of serums and drugs to persons who may have been exposed to a disease. Processes such as pasteurization also fall in this category as they are universally applied to materials which, if tested, would not require pasteurization. The present specification at page 5, lines 19 - page 6, line 4 clearly makes the point that the broad based use of the disclosed product as a diet can prevent or reduce the overall incidence of insulin dependent diabetes.

Claim 28 points out a composition that may be used as a dietary or pharmaceutical product, the use of which is taught in the present specification.

Claims 35 and 36 point out that the method is concerned with the --inhibition of the inductive effect of beta casein and its fragments-- on insulin dependent diabetes. This method is enabled by the present specification. At page 4, lines 18-24 it is disclosed that certain caseins are responsible for the "induction of an immune response towards beta casein". The specification also discloses the effect on the prevention of insulin dependent diabetes when beta casein is avoided in the diet of infants and newborns. In the absence of evidence to the contrary, the applicant's assertion of utility should be accepted as providing a basis for how to make and use the invention.

The instant rejection is based on a statute that requires an applicant for a patent to provide sufficient information that would enable one skilled in the art to make and use the invention. No issues has been raised with regard to the detailed information as to how to make the product of the invention. The information as to how to use the product is implicit in the disclosure that the modified casein is used as an infant food in the same manner that unmodified casein is used. Thus, there cannot be any serious question regarding the fact that the applicant has taught the art how to make and use the invention.

The thrust of the Examiner's arguments is that "the specification does not provide any teachings that show that administration of the product as claimed would prevent or inhibit the onset of IDDM".

MPEP§2107.01 (Rev. 1, Feb 2003) discusses at length the relation between Section 101 and Section 112, first paragraph. All that is required by 35 U.S.C.§101 is that some use for the claimed invention must be set forth in the specification. This has been done in the present specification. The requirements of 35 U.S.C.§112, first paragraph may only be properly used to reject patent claims if one skilled in the art could not practice the claimed invention based on the disclosure. The Examiner has urged that an unreasonable amount of experimentation would be required for one to "make and/or use the claimed invention and methods of using the same" (prior Office Action, page 6). Attention is directed to MPEP§2164.01(c) (Rev. 1, Feb 2003) which

points out that "if a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 U.S.C.§112 is satisfied. In the present case, it is apparent that this standard has been met.

If the rejection is maintained, it is requested that the Examiner provide additional comments regarding what experiments are deemed to be necessary and how such experiments would constitute unreasonable experimentation in order for one skilled in the art to use the claimed invention.

In virtually every patent for a new pharmaceutical compound, the disclosure regarding utility merely states a condition, a host, a dose and sometimes a route of administration for the new chemical compound. There are typically no reports of clinical studies, toxicology, stability, side effects, drug interactions etc. which are required by the FDA as a basis for the approval of the sale of the new chemical compound for use in humans. The courts have repeatedly instructed the PTO that human clinical data is not required to establish utility. Cf. MPEP§2107.03 If human clinical data is unnecessary to establish utility, it is not seen how such data would be necessary to satisfy the "how to make and use" standard of 35 U.S.C.§112, first paragraph.

The province of drug safety and efficacy belongs to the FDA and not to the PTO. See In re Brana, 34 USPQ2d 1436 (Fed. Cir. 1995) and MPEP§2107.01 (Rev. 1, Feb 2003)

The Examiner has not cited the previously cited decision in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988) in support of the present rejection and it is assumed that the Wands factors are not being relied upon in support of the present ground of rejection.

The Examiner has not cited any missing information regarding the "how to make and use" requirements of U.S.C.§112, first paragraph. The question of the operability of the claimed method is not properly raised under 35 U.S.C.§112, first paragraph unless reasons can be given that are directed to the lack of information as to how to carry out the invention.

In order to show usefulness, it is not necessary to show

statistically significant data relating to the alleged use. Nelson v. Bowler, 206 USPQ 881,883 (CCPA 1980). If it is not necessary to show statistically significant data to show usefulness, statistically significant data should not be required for the purpose of showing compliance with 35 U.S.C.§112, first paragraph.

The Applicant wishes the Examiner to again consider the following materials, as showing the state of the art, with regard to the present invention:

1. Research Grant 1 RO1 HD40364-01 of $1.8 million from the NIH to study whether a cow's milk hydrolysate (not containing beta casein) is able to prevent the onset of insulin dependent diabetes.

2. J. Endocrinology, (2003) 176, preprint of peer reviewed article which reports the enhanced cellular immune response to bovine beta casein in Type 1 diabetes patients.

3. Hormone and Metabolic Res. (2002) 34,455, peer reviewed article which reports on the development of Type 1 diabetes by a genetic background through exposure to cows milk.

The research grant from the National Institutes of Health is evidence that the applicant has established that the subject of that trial is reasonably predictive of having the asserted therapeutic utility See MPEP §2107.02 (Rev. 1, Feb. 2003). The NIH trial should be accepted as a sufficient basis for the withdrawal of the Examiner's statements that:

> [T]he Examiner has presented the unpredictable state of the art with regard to the various factors that could be potentially involved in the pathogenesis of IDDM ...(emphasis added)
>
> [T]he present rejection is directed to the lack of teachings, guidance or working examples provided by the specification for showing that administration of the claimed dietary product would prevent IDDM in an individual (emphasis added).

Since the Examiner has raised the question of whether or not the administration of the claimed dietary product would prevent IDDM in an individual, the NIH study should be considered

as being probative of a prima facie case that the claimed dietary product prevents IDDM. NIH studies, which require the expenditure of government funds, are only carried out if the leading experts in the field believe that the preliminary data shows that the method is expected to be successful.

Publications 2 and 3 provide additional evidence of peer acceptance of the invention and also provide data that corroborates the existence of a scientific basis on which the results provided by the invention can be explained. For these reasons, it is requested that the amended claims be favorably considered.

New claims 37-41 point out the invention as a "product" without reciting any intended use. If an enabled use is present for a compound or composition, which may be correlated with the entire scope of the claim, a rejection for lack of enablement is precluded. MPEP§2107(c), last paragraph (Rev. 1, Feb 2003). New claims 42-46 point out a dietary product. These claims are enabling based on the uncontroverted fact that beta casein is a nutritive protein and there is no reference in the claim to the use of the composition as a pharmaceutical. New claims 47-51 point out a method inhibiting molecular mimicry of GLUT2. These claims are based on the original claims and on the specification at page 1, line 22 to and including page 2, line 23.

The objection to claim 36 is traversed as it is not necessary to provide each detail of a process in order to point out the invention. The claim as presented points out the invention and it is not necessary to recite the step of expressing the gene in order to point out the invention.

An early and favorable action is earnestly solicited.

Respectfully submitted,

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